Supreme Court, U.S.
FILED
NOV 20 1985
JOSEPH F. SPANIOL, JR.
CLERK

No. 85-664

IN THE
# Supreme Court of the United States
October Term, 1985

FRANK YOUNG, Commissioner of Food and Drugs,
*Petitioner,*

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
*Respondents.*

**On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit**

## BRIEF OF AMICI CURIAE AMERICAN FEED INDUSTRY ASSOCIATION AMERICAN MEAT INSTITUTE NATIONAL BROILER COUNCIL NATIONAL COTTONSEED PRODUCTS ASSOCIATION NATIONAL TURKEY FEDERATION IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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## STATEMENT OF INTEREST

Amici submit this brief in support of the petitioner Frank Young, Commissioner of Food and Drugs. Consent to file this brief has been obtained from counsel for all parties and has been filed with the Clerk of this Court.

The several trade associations joining in this brief are spokesmen for a broad array of agricultural interests that will be adversely affected if the court of appeals' decision is allowed to stand. The American Feed Industry Association is the national trade association representing the interests of those involved in the production and sale of animal and poultry feeds. The American Meat Institute is the national trade association representing packers and processors of red meat and red meat products. Its nearly 500 members produce and ship meat products throughout the United States and internationally. The National Broiler Council is the national trade association whose members represent the processors of more than 80 percent of the chicken consumed in the United States, as well as a significant number of companies that supply feed, packaging material and other products necessary in the production of chicken. The National Cottonseed Products Association is the national organization of firms and individuals engaged since its founding in 1897 in the processing of cottonseed and the marketing of its products, which include cottonseed meal, a rich source of protein which is used as a feed for livestock. The National Turkey Federation is the national trade association representing producers of turkeys and turkey products.

As the Government recognized in its Petition, "[i]n the production of food, it is often impossible to avoid the presence of small quantities of added substances that may be harmful to human health if taken in sufficient amount." (Pet. at 7.) Amici agree and accordingly are concerned that the court of appeals' decision in *Community Nutrition Institute v. Young* will have far reaching and adverse effects on American agriculture. The presence of ubiquitous environmental contaminants in raw agricultural commodities has implications which extend far beyond the crops themselves. An examination of the various stages of the food chain from growing crops to manufacturing meat and poultry products illustrates the pervasive effect of the court of appeals' decision on products containing minute quantities of unavoidable environmental contaminants.



Environmental contaiminants can be present at low levels even in the seed purchased by the farmer, and they remain in the crop as it matures. Crops can become further contaminated prior to harvest from natural contaminants such as aflatoxin,[1] or by contaminants which have been placed in the environment by man. When the crops are harvested and first processed, some environmental contaminants can be removed. However, despite the use of state-of-the-art equipment and processes, some contaminants such as aflatoxin cannot be totally eliminated by current manufacturing practices. To the extent the contaminants cannot be removed, it is imperative that the farmer or processor have guidance in determining whether the trace amounts of the contaminant are above the safety threshold so as to render the product adulterated under the Federal Food, Drug, and Cosmetic Act ("FDCA"). In the absence of such guidance, the processor is given the unwelcome choice of either destroying the crop if any residue is found or to ship and take the risk that the Food and Drug Administration ("FDA") would initiate regulatory action against the processor's shipment.[2]

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[1]Aflatoxin is a carcinogenic mold by-product commonly found on such crops as corn, cotton, and peanuts.

[2]The shipment of "adulterated" food can subject the responsible individuals to criminal penalties pursuant to Section 303 of the FDCA, 21 U.S.C. § 333, or an injunction pursuant to Section 302 of the FDCA, 21 U.S.C. § 332. In addition, the "adulterated" product is subject to seizure and condemnation under Section 304 of the FDCA, 21

*(continued)*

This dilemma follows the product throughout the various steps of the food chain. After the product has been initially processed, it may go to a feed manufacturer for conversion to animal feed. Once again, if the substance cannot be totally removed by the processing, as if often the case, the feed manufacturer must either destroy or ship the product which may be subject to regulatory action.

The animal feed is given in turn to food-producing animals. Altnough certain environmental contaminants in animal feed are not transferred to the animal tissue, some environmental contaminants, such as the pesticide dieldrin, can be passed through to animal tissue.[3] Additionally, grazing animals may pick up contaminants directly from the pasture.

Finally, for those animals sent to slaughter, the Food Safety and Inspection Service of the United States Department of Agriculture ("USDA") conducts continuous inspection of meat and poultry products under the Poultry Products Inspection Act ("PPIA"), 21 U.S.C. §§ 451-470, and the Federal Meat Inspection Act ("FMIA"), 21 U.S.C. §§ 601-695. If an environmental contaminant, such as dieldrin, is discovered in the animal tissue, the inspector must make the decision as to whether the meat is adulterated and should be condemned under these laws. Unfortunately, the court of appeals' decision may lead the USDA

U.S.C. § 334. Furthermore, the criminal penalty could be up to $100,000 per violation, 18 U.S.C. § 3623. Finally, if the court of appeals' decision stands, there is a great concern that because foods containing trace innocuous levels of environmental contaminants may be considered technically adulterated, unjustified product liability suits may be initiated.

[3]These foods are regulated by Section 402(a)(1) of the FDCA under the "may render injurious" standard applicable to environmental contaminants. 39 Fed. Reg. 42,743, 42,745 (Dec. 6, 1974).



inspector to conclude that, unless a formal tolerance has been established for this unavoidable contaminant, the product must be condemned and destroyed.

In sum, the court of appeals' decision leaves everyone from the seed producer to the farmer to the USDA inspector with no guidance as to what levels of an unavoidable contaminant may render a food adulterated under the FDCA, FMIA, or PPIA. At its worst, the court's decision declares that most products in the food chain are adulterated. At its best, the decision denies guidance to the agricultural industry and those who regulate it.

## PROCEEDINGS BELOW

Two public interest groups and a consumer brought this suit in the United States District Court for the District of Columbia to challenge a decision of the FDA that corn containing certain levels of aflatoxin when used for certain well-defined purposes would not render the corn injurious to health. In this suit, Respondents asserted that FDA should not have proceeded as it did; rather it was mandated under Section 406 of the FDCA, 21 U.S.C. § 346, to establish formal tolerances through formal adjudicative rulemaking. The district court granted summary judgment in favor of FDA, holding that the agency has discretion on whether to proceed through informal action levels or whether it should proceed through the formal tolerance system set forth in Section 406 of the FDCA.

The court of appeals reversed, holding that FDA may not proceed by action levels rather than tolerances established through formal rulemaking procedures, pursuant to Section 701(e) of the FDCA, 21 U.S.C. § 371(e). In reaching its conclusion, the court focused first on the language of Section 406 of the FDCA, which states that a product

containing an avoidable added poisonous or deleterious substance is unsafe (and hence adulterated under Section 402(a)(2)(A) of the FDCA). For unavoidable substances, the Secretary of Health and Human Services can promulgate a formal tolerance (*i.e.*, establish a maximum amount of contaminant permitted in the product). The court read this authority as mandating formal tolerances for all unavoidable substances and then concluded that FDA could not circumvent the procedures required for establishing such tolerances (*i.e.*, formal rulemaking) through the exercise of its administrative discretion.

## ARGUMENT

### I. THE COURT OF APPEALS' INTERPRETATION OF THE FDCA RENDERS ALMOST ALL FOODS ADULTERATED

Both the Government and other amici have addressed the critical issue of the interplay among Sections 402(a)(1), (a)(2)(A), and 406 of the FDCA, and amici will not repeat those arguments here. But by refusing to recognize the important statutory role played by Section 402(a)(1), the court of appeals has, in essence, ruled that where the establishment of a Section 406 tolerance is technically warranted, and where no formal tolerance is in effect for a food containing an unavoidable poisonous or deleterious substance such as aflatoxin, the food is adulterated. (Pet. App.7a.)[4]

[4]This ruling contravenes the plain language of the statute. Section 406 addresses only two discrete situations. First, any poisonous or deleterious substance which is unnecessary or avoidable renders the product adulterated under Section 402(a)(2). Second, if a formal tolerance for a necessary or unavoidable contaminant is established, a product containing levels of the contaminant in excess of the tolerance is adulterated under Section 402(a)(2). Section 406 does not deal with poisonous or deleterious substances which are unavoidable and for which no tolerance is established.



The court of appeals' decision would condemn unnecessarily much of the nation's food supply, from raw agricultural commodities such as corn and cottonseed meal, to processed foods containing these products. The court of appeals' interpretation of the FDCA has created a problem where none exists, disparaging the FDA's enforcement of the FDCA and raising unwarranted fears for consumers.

### II. IMPLEMENTATION OF THE COURT OF APPEALS' HOLDING IN THIS CASE WOULD BE ESPECIALLY DISRUPTIVE FOR MEAT AND POULTRY PRODUCTS AS REGULATED BY USDA

The holding of the court of appeals presents particularly serious ramifications as it relates to the regulation of meat and poultry products. USDA is primarily responsible for ensuring the safety and wholesomeness of these products and their ingredients. Yet, while reserving the right to make judgments as to the appropriateness of food substances as used in meat and poultry products, USDA generally relies upon FDA for the initial approval of food ingredients and basic determinations as to their safety. In this regard, the FMIA and PPIA, the statutes from which USDA draws its regulatory authority over meat and poultry products, and the regulations promulgated by USDA thereunder, make clear the interlocking responsibilities of USDA and FDA over food substance safety and use.

USDA has adopted informal action levels for a variety of environmental contaminants following consultation with FDA. Given the similarity in content of USDA and FDA action levels, to render nugatory the action levels informally established for environmental contaminants by FDA could render adulterated a multitude of meat and poultry products containing low levels of environmental contaminants. Invalidation of action levels may lead to the

condemnation of any meat or poultry product in which an environmental contaminant is detected.

### A. The Meat and Poultry Inspection Acts Declare As Adulterated Products Containing "Poisonous or Deleterious" Substances; USDA Relies on FDA to Make Preliminary Safety Assessments for Environmental Contaminants

Like the FDCA, both the FMIA and PPIA declare as adulterated meat and poultry products that (1) bear or contain any poisonous or deleterious substance which may render them injurious to health or (2) bear or contain any added poisonous or added deleterious substance (other than one which is (a) a pesticide chemical in or on a raw agricultural commodity; (b) a food additive; or (c) a color additive) which may, in the judgment of the Secretary, make such articles unfit for human food. 21 U.S.C. §§ 601(m) and 453(g). Further, such products are rendered adulterated under those statutes if they bear or contain any food additive, color additive or, in the case of a raw agricultural commodity, pesticide chemical which is deemed unsafe within the meaning of FDCA. 21 U.S.C. §§ 601(m)(2)(B), (C), (D). The terms "pesticide chemical," "food additive," "color additive" and "raw agricultural commodity" have the same meanings for purposes of the FMIA and PPIA as they do so under the FDCA. 21 U.S.C. §§ 601(r), 453(y). Finally, both the FMIA and PPIA, like the FDCA, prohibit the sale, transport, offer for sale or transportation, or receipt for transportation in commerce of any adulterated articles. 21 U.S.C. §§ 610 (b)(1)(B), 458(a)(2)(A).

Although both the FMIA and PPIA specifically declare adulterated any meat or poultry product containing any



food additive, color additive or pesticide chemical that FDA has deemed unsafe, those statutes do not automatically declare as adulterated products containing environmental contaminants for which FDA has not established tolerances pursuant to Section 406 of the FDCA, 21 U.S.C. § 346. At least with respect to environmental contaminants, USDA retains the authority to determine on a case-by-case basis whether the presence of a contaminant renders such meat or poultry product "unfit for human food" within the meaning of the FMIA and PPIA. *See* 21 U.S.C. §§ 601(m) and 453(g). Theoretically, USDA is permitted to find a meat or poultry product containing a contaminant declared unlawful by *CNI v. Young* not to be adulterated, provided the presence of the contaminant does not, in USDA's opinion, render the product "unfit for human food."

From a practical standpoint, however, the close similarity between USDA's and FDA's "action levels" with respect to environmental contaminants – and the elimination of all "action levels" in light of the court of appeals' decision – would make USDA's decisionmaking process in this area at least chaotic and perhaps impossible.

### B. Because USDA Must Inspect and Approve Every Meat and Poultry Product, It Has Virtually No Discretion to Overlook the Presence of Environmental Contaminants

Within certain limits, FDA has discretion to focus its enforcement resources by taking regulatory action against only those products containing "poisonous or deleterious" substances that present a hazard to human health. USDA, on the other hand, is under a statutory obligation to inspect and, in effect, certify as unadulterated every meat and poultry product before it may be shipped in com-

merce. The FMIA and PPIA require USDA to inspect and either affirmatively approve or prohibit shipment of all meat and poultry products prepared for commerce. 21 U.S.C. §§ 603-606, 621 and 457. Furthermore, an establishment's shipment in commerce of meat or poultry products that have not been "inspected and passed" is specifically prohibited by the FMIA and PPIA. 21 U.S.C. §§ 610(d)(2), 458(a)(2)(B).

In summary, implementation of the court of appeals' holding could disrupt the marketing of meat and poultry products more than any other foods. In establishing a continuous and mandatory inspection system under the FMIA and PPIA, Congress has unequivocally directed that USDA ensure that meat and poultry products bearing the USDA "Inspected and Passed" legend contain only those substances that have specifically been approved by FDA, unless USDA has affirmatively concluded that such substances do not render the products "unfit for human food." If FDA must establish such levels for environmental contaminants through formal rulemaking procedures, rather than informally as "action levels," any meat or poultry product containing environmental contaminants for which formal tolerances have not yet been established may not legally be approved for shipment in commerce unless and until USDA makes the independent determination that the contaminants would not adulterate the product.

In its holding the court of appeals suggested that its impact could be minimized through enforcement restraint. While this approach, as outlined by the other amici, is highly unsatisfactory, it is not a viable option for manufacturers of meat and poultry products. To the contrary, the court's ruling would either force the wholesale con-



demnation of these staples of the food supply or lead to widespread confusion and loss of public confidence in the mark of federal inspection which accompanies such products in commerce. This Court should act to avoid placing the industry, the government and consumers in such an untenable position.

## CONCLUSION

For the foregoing reasons, the Petition for Writ of Certiorari should be granted.

Respectfully submitted,

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November 1985